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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Philipp Lang

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IMAGING THERAPEUTICS, INC.

c/o KENYON & KENYON

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SUITE 600

SAN JOSE, CA 95110-2731

EXAMINER

LU, TOM Y

ART UNIT

PAPER NUMBER

2621

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,528

Applicant(s)

LANG, PHILIPP

Examiner

Tom Y. Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-10, 12-31 and 48-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-10, 12-31 and 48-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment and written response filed on 5/26/2005 has been entered and considered.
2. Claims 5-7, 11 and 32-47 have been cancelled.
3. Claims 51-55 have been added.

Information Disclosure Statement

4. The Information Disclosure Statement (IDS) filed on 5/26/2005 has been considered.

Response to Arguments

5. Applicant's arguments filed on 5/26/2005 have been fully considered but they are not persuasive.

The Sachdeva reference:

Applicant argues the Sachdeva reference does not produce an image of bone, essentially, applicant disagrees that teeth are bones because Sachdeva teaches an image of teeth. Upon further review of specification, and in light of applicant's arguments, the examiner respectfully, disagrees as follows: teeth are bones as defined by Merriam-Webster's Collegiate Dictionary, "tooth: one of the hard bony appendages...", (a copy of definition from the dictionary is attached). The examiner notes applicant has submitted a non-patent literature document to define bone structures, however, the examiner further notes there is no evidence in the document as to claim teeth are not bones. Based on the broadest reasonable interpretation, and according to the definition in Merriam-Webster's Dictionary, the examiner believes it is appropriate to interpret an image of teeth in the Sachdeva reference as "an image of bone". Moreover, as seen in

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applicant's own drawings, the examiner believes applicant's own invention is directed to X-ray images of teeth, which is rather puzzling to the examiner as to the arguments raised in this Response. Additionally, applicant's argues the X-ray image of bone in Sachdeva does not transmit over to a remote computer, the examiner notes at column 3, line 67 and column 4, lines 1-6, the Sachdeva reference teaches sending digital information including x-ray images of an patient's teeth to a remote server.

6. Applicant's arguments, see Remarks, pages 8-9 under "Claim rejections under 35 U.S.C. 112" section, filed 5/26/2005, with respect to claims 9-10 have been fully considered and are persuasive. The rejection under 35 U.S.C. 112 2nd Paragraph of claims 9-10 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 8-10, 12, 18-20, 22-26 and 51-52 rejected under 35 U.S.C. 102(e) as being anticipated by Sachdeva et al (U.S. Patent No. 6,315,553 B1).

- a. Referring to Claim 1, Sachdeva discloses providing a digitized x-ray image (Sachdeva at column 8, line 64, teaches providing digital information of the x-rays of jaws, column 4, lines 1-3) on a local computer (site orthodontic system 12 is the claimed "local computer"), wherein the x-ray image includes an image of bone (teeth are bones); transmitting the x-ray image to a remote computer (the

scanned digital image information is routed through communication network 16 to orthodontic server 14, column 9, lines 24-26; the orthodontic server 14 herein is the claimed “remote computer”); and analyzing the x-ray image at the remote computer, thereby deriving quantitative information on bone from the x-ray image (Sachdeva at column 6, lines 45-48, teaches the digital x-ray images are analyzed to generate orthodontic parameters and a digital model, which is the claimed “quantitative information”).

- b. Referring to Claim 2, Sachdeva discloses wherein the analysis of the x-ray image comprises using a computer program on the remote computer (a computer program must be required to generate a digital model on the server 14).
- c. Referring to Claim 3, Sachdeva discloses wherein the quantitative information is densitometric information (one of the orthodontic parameters is bone density, column 13, line 52).
- d. Referring to Claim 4, Sachdeva discloses wherein the densitometric information is bone mineral density (column 13, line 52).
- e. Referring to Claim 8, Sachdeva discloses wherein said quantitative information is information on the morphology of the bone (a digital model of teeth is a orthodontic structure, which is information on the morphology of the bone, column 12, line 47).
- f. Referring to Claim 9, Sachdeva discloses wherein said information on the morphology of a structure is information on the two-dimensional arrangement of

individual components forming said structure (column 16, line 45; note the individual components herein are teeth as shown in figure 3).

- g. Referring to Claim 10, Sachdeva discloses wherein said information on the morphology of a structure is information on the three-dimensional arrangement of individual components forming said structure (column 16, line 44).
- h. Referring to Claim 12, Sachdeva discloses wherein said information is selected from the group of consisting of trabecular thickness, trabecular spacing; two-dimensional or three-dimensional spaces between trabecular; two-dimensional or three-dimensional architecture of the trabecular network (column 12, line 41, Sachdeva teaches the orthodontic structures includes gums, which is the claimed “trabecular”, and the structure of gums determines the two-dimensional or three dimensional spaces between gums).
- i. Referring to Claim 18, Sachdeva discloses wherein the x-ray image further comprises one or more internal standards (the internal standard in Sachdeva is density of bone, for example, jaw as shown in figure 3, column 13, line 52).
- j. Referring to Claim 19, Sachdeva discloses wherein the internal standard is density of a tissue of a human or air surrounding a structure (a jaw contains gums and teeth, which are tissues).
- k. Referring to Claim 20, Sachdeva discloses wherein the internal standard is density of a tissue and the tissue is selected from the group consisting of subcutaneous fat, bone and muscle (column 12, lines 40-42).

- l. Referring to Claim 22, Sachdeva discloses generating a diagnostic report based on the quantitative information (Sachdeva at column 10, line 13, teaches a diagnostic support module 88, which generates the corresponding information that is derived from the “quantitative information”; note the corresponding information input the simulator 84 is the claimed “diagnostic report”).
- m. Referring to Claim 23, Sachdeva discloses wherein said diagnostic report provides information on a patient’s state of health (column 10, lines 40-41).
- n. Referring to Claim 24, Sachdeva discloses wherein the state of health is selected from the group consisting of bone mineral density status and fracture risk (column 13, line 52).
- o. Referring to Claim 25, Sachdeva discloses generating a bill for the diagnostic report (column 8, line 67, billing system is incorporated, and such billing system communicated through Internet as well, therefore, it is a computer software system. And the billing system integrates the services provides by the orthodontic office and the manufacture, and since the diagnostic report mentioned above is on the manufacture side, therefore, the billing of the diagnostic report is also included).
- p. With regard to Claim 26, see explanation in Claim 25.
- q. Referring to Claim 51, the examiner notes bone density is structural information because density is mass/volume, and volume is to be considered as structural information.
- r. With regard to Claim 52, see explanation in Claim 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 13-17 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva et al in view of Pavloskaia et al (U.S. Patent No. 6,463,344 B1). The arguments in Paragraph 3.a above as to the applicability of Sachdeva are incorporated herein.

- a. Referring to Claim 13, Sachdeva teaches transmitting digital information to the server 14 to generate a digital model, which is based on the scanned image data and the x-ray image. However, Sachdeva does not explicitly teach what type of scanned image data it is, and how the digital model is constructed in details, therefore, lacking so-called "acquisition parameters". Pavloskaia at column 4, lines 29-31, teaches using 3-dimensional x-ray image data to generate a digital model as shown in figure 3. And such model regeneration after network transmission requires compressed data associated with the model, column 6, lines 36-59, and the compressed data is the claimed "acquisition parameters" because the compressed data includes camerapoint, focus point/distance, column 10, lines 1-3, and line 38. At the time the invention was made, a person of ordinary skill in the art would have been motivated to transmit x-ray acquisition parameters to a remote computer to construct a digital model because Pavloskaia teaches generation of a digital model requires focal point/distance, and Sachdeva also needs to generate a digital model, which also requires x-ray images, and

both models are 3-dimensional models, and they must both require focus point/distance for generation.

- b. Referring to Claim 14, whether the acquisition parameters transmitted prior to the remote computer prior to, simultaneously or after the x-ray image does not affect the generation of the digital model, thus it carries not patentable weights. In addition, the applicant does not state transmitting the parameters prior to, simultaneously or after the x-ray image would post any significant advantage or solve any particular problem. Therefore, the examiner herein takes official notice that the combination of Sachdeva and Pavloskaia can transmit the parameters prior to, simultaneously or after the x-ray image.
 - c. With regard to Claim 15, see explanation in Claim 14.
 - d. With regard to Claim 16, see explanation in Claim 14.
 - e. With regard to Claim 17, one of the x-ray acquisition parameters, focus distance, is addressed in Claim 13.
9. Claims 21 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva et al. The arguments in Paragraph 3.a above as to the applicability of Sachdeva are incorporated herein.
- a. Referring to Claim 21, Sachdeva teaches using Internet to transmit digital information from system 12 to server 14. Although Sachdeva does not explicitly teach the transmission contains encryption, a person of ordinary skilled in the art would know that any transmission through Internet contains some kind of encryption for security purposes. An official notice is taken herein that Sachdeva's information transmission incorporates encryption.

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- b. Referring to Claim 27, Sachdeva teaches providing digital information of x-rays, column 4, line 3. Although, Sachdeva does not explicitly teach wherein the x-ray image is an x-ray film, it would be reasonable for a person of ordinary skilled in the art to assume that digital information of x-ray is derived from an x-ray film.
- c. With regard to Claim 28, see explanation in Claim 27.
- d. With regard to Claim 29, the examiner takes official notice that a film is digitized using a scanning unit because it is well known in the art to convert an x-ray film to x-ray image through scanning.
- e. With regard to Claim 30, whether the x-ray image is acquired digitally, or using conversion from x-ray film to x-ray image does not alter the scope of the invention, the examiner take official notice herein that the x-ray images in Sachdeva can be acquired digitally.
- f. With regard to Claim 31, the examiner takes official notice that the x-ray film image is acquired using selenium detector system or a silicon detector system because how the x-ray image is acquired in this invention does not carry any patentable weight, and it would have been obvious to a person of ordinary skilled in the art to use any x-ray detector system to accomplish the same goal of obtaining an x-ray film, and later perform digitizing process to generate an digitized x-ray image.

10. Claims 48-50 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva et al in view of Stein et al (U.S. Patent No. 5,657,369). The arguments in Paragraph 3.a above as to the applicability of Sachdeva are incorporated herein.

- a. Referring to Claim 48, Sachdeva teaches transmitting x-ray image to server 14 for diagnostic report. However, Sachdeva does not explicitly teach diagnosing osteoporosis based on the x-ray image. However, Stein at column 1, lines 20-25, teaches it is well known in the art to use x-rays to measure the density and distribution of bone to help professionals to diagnose osteoporosis. Since Sachdeva also measure the density of bone, column 13, line 52, a person of ordinary skilled in the art would be motivated to use such density information to diagnose diseases like osteoporosis, and it is noted that Sachdeva's system also contains a remote site 56, where a specialist is retained to analyze and provide medical treatments.
- b. Referring to Claim 49, the combination of Sachdeva and Stein teaches administering suitable treatment to osteoporosis (Sachdeva teaches physicians providing treatment related to patients' medical conditions, column 10, line 40-41).
- c. With regard to Claim 50, the examiner takes official notice that upon diagnosing osteoporosis, a person of ordinary skilled in the art would provide treatment such as an anti-resorptive agent or an anabolic agent.
- d. With regard to Claim 53, see explanation of Claim 48.
- e. With regard to Claim 54, see explanation of Claim 49.
- f. With regard to Claim 55, see explanation of Claim 50.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y. Lu whose telephone number is (571) 272-7393. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mancuso can be reached on (571)-272-7695. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Tom Y. Lu

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